Our Case No. 10743-6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
Keith Wood et al.	)	
Serial No. **09/813,279**	)	Examiner: **Louise N. Leary**
Filing Date: **March 19, 2001**	)	Group Art Unit No. **1654**
For **METHOD FOR DETECTION OF ATP**	)	

DECLARATION UNDER 37 C.F.R. 1.132

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

SIR:

I, Keith Wood, declare and state that:

1. I am an inventor of "METHOD FOR DETECTION OF ATP" of U.S. Patent Application Serial No. 09/813,279, cited above.

2. I have read the above-identified application, the Office Action of November 28, 2003 and the references cited therein, and the Amendment filed August 22, 2003.

3. "There are multiple variations of cellular ATP detection methods currently used, all of which act in a *stepwise* manner. Some such methods first lyse the cells and inactivate the ATPase activity endogenous to the sample

(e.g., by increasing sample pH), then neutralize the ATPase inhibitor, thereby converting the environment of the sample to one favorable to luciferase activity prior to adding the luciferase and detecting luminescence. Other such methods combine the neutralization of the ATPase inhibitor with the addition of luciferase. *There are no ATP detection systems that provide* a composition or method capable of inactivating endogenous ATPase activity and detecting luciferase activity *in the same environmental milieu.* Therefore, *current assays that use luminescence to detect ATP are handicapped by the need for successive, time-consuming steps.*" (Specification of Application Ser. No. 09/813,279, as filed on March 19, 2001, at page 3, line 29 – page 4, line 7, emphasis added)

4. Methods using these novel compositions to detect ATP in a sample by reducing the steps of cell lysis, endogenous ATPase inhibition, and substrate and luciferase addition *to a single step* that is then followed by detection of the resulting luminescence." (Specification of Application Ser. No. 09/813,279, as filed on March 19, 2001, at page 10, lines 7-10, emphasis added)

5. The invention described in the specification originally filed as application 09/813,279 on March 19, 2001 provides, among other things, that "[t]he methods comprise adding to a sample a composition ("reagent composition") comprising a luciferase enzyme and an ATPase inhibitor, and detecting luminescence produced in the sample by the conversion of a substrate into a luminescing compound by luciferase. The reagent composition has properties of enhanced stability, *thereby eliminating the traditional step of inhibiting ATPases endogenous to a sample before adding luciferase enzyme to the sample.* Thus, although luciferase functions as an ATPase, while in the reagent composition it is resistant to the effects of an ATPase inhibitor also present in the reagent composition. Such stable reagent compositions facilitate many ATP detections in a

sample over a long period of time as well as detection of ATP in many samples over a long period of time. (Specification of Application Ser. No. 09/813,279, as filed on March 19, 2001, at page 4, lines 19- 29, emphasis added)

6. In the *single-step* ATP assay of the invention, all of the necessary components of the ATP-dependent enzyme (*e.g.,* luciferase), such as the enzyme, substrates, and ATPase inhibitors are comprised within a reagent composition and *are added to a sample at once.* (Specification of Application Ser. No. 09/813,279, as filed on March 19, 2001, at page 11, lines 4-6, emphasis added)

7. The undersigned petitioner declares further that all statements made herein and in U.S. Patent Application Ser. No. 09/813,279, as filed on March 19, 2001, are, to his own knowledge, true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Jan 30, 2004
Date

Keith Wood
Inventor and Applicant